

**Attachment 1****AUG 16 2007****Summary of Safety and Effectiveness**Page 1 of 3

This 510(k) summary of Safety and Effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h)

**General Information:**

Trade Name:	NeuViz Dual Multi-slice CT Scanner System
Common Name:	CT Scanner
Classification Name:	21 CFR Part 892.1750 Computed Tomography X-ray System
Classification:	Class II
Performance Standard:	21 CFR Subchapter J, Federal Diagnostic X-ray Equipment Standard  IEC/EN 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety  IEC/EN 60601-1-1, Medical electrical equipment--Part 1:General requirements for safety-1. Collateral Standard: Safety requirements for medical electrical systems  IEC/EN 60601-1-2, Medical electrical equipment--Part 1:General requirements for safety-2. Collateral Standard: Electromagnetic compatibility—Requirements and tests  IEC/EN 60601-1-3, Medical electrical equipment--Part 1:General requirements for safety-3. Collateral Standard: General requirements for radiation protection in diagnostic X-ray equipment

IEC/EN 60601-1-4, Medical electrical equipment--Part 1:General requirements for safety-4. Collateral Standard: Programmable electrical medical systems

IEC/EN 60601-2-28, Medical electrical equipment--- Part 2:Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis

IEC/EN 60601-2-32, Medical electrical equipment--- Part 2:Particular requirements for the safety of associated equipment of X-ray equipment

IEC/EN 60601-2-44, Medical electrical equipment--- Part 2:Particular requirements for the safety of X-ray equipment for computed tomography

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Manufacture: PHILIPS AND NEUSOFT MEDICAL SYSTEMS CO., LTD.  
Neusoft Park, Hun Nan Industrial Area, Shenyang 110179,  
P.R.China

Distributor: NEUSOFT MEDICAL SYSTEMS CO., LTD.  
No.3-11,Wenhua Road, Heping District,  
Shenyang, P.R.China  
Post Code : 110004

Submitter: Contact : Tianyanfang  
Title : Manager of Q&R Department  
Tel : 86-24-83660649  
Fax : 86-24-83780480  
E-Mail : [Tianyanfang@neusoft.com](mailto:Tianyanfang@neusoft.com)

Summary prepared : May 19<sup>th</sup>, 2006

## Safety and Effectiveness information

### Intended Uses:

The NeuViz Dual Systems (modified) are intended to produce cross-section images of head and whole body by computer reconstruction of X-ray transmission data taken at different angles.

### Device Description:

The NeuViz Dual Systems (modified) are whole body X-ray computed tomography scanner which features a continuously rotating tube-detector system and multi-slice capability of 2 slices simultaneously. The system software is an interactive program used for X-ray scan control, image reconstruction, and image archive/evaluation.

### Predicated Device:

K062451: NeuViz Dual Systems  
K033326: Philips Plus CT Scanner

### Statement of Substantial Equivalence:

The NeuViz Dual (modified) systems are of comparable type and substantially equivalent to the NeuViz Dual system (K062451) and the "Philips Plus" CT Scanner (K033326) that comply with the same or equivalent standards and have the same intended uses. All of these system use on-board high frequency High-Voltage generator to generate X-radiation from X-ray tube. The X-ray transmission data is detected by the detector and is reconstructed by the computer which has an interactive user interface. All of these devices produce two dimensional image and 3D image that can be filmed or electronically stored for future review.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
9200 Corporate Blvd.  
Rockville MD 20850

Mr. Tian Yanfang  
Manager of Quality Management Department  
NEUSOFT Medical Systems Co., Ltd.  
No. 3-11, Wenhua Road, Heping District  
Shenyang, Liaoning 110004  
P. R. CHINA

AUG 16 2007

Re: K071308

Trade/Device Name: NeuViz Dual Multi-slice CT Scanner System  
Regulation Number: 21 CFR 892.1750  
Regulation Name: Computed tomography x-ray system  
Regulatory Class: II  
Product Code: JAK  
Dated: July 11, 2007  
Received: August 9, 2007

Dear Mr. Yanfang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.



*Protecting and Promoting Public Health*

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

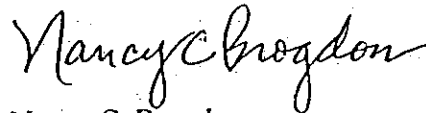
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

Attachment 2

Indications for Use

510(k) Number: K071308

Device Name: NeuViz Dual Multi-slice CT Scanner System

The NeuViz Dual Systems (modified) are intended to produce cross-section images of head and body by computer reconstruction of X-ray transmission data taken at different angles.

Prescription Use YES

Over-The-Counter Use NO

(Part 21 CFR 801 Subpart D)

(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF DEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

JW Chang  
(Division Sign-Off)  
Division of Reproductive, Abdominal and  
Radiological Devices  
510(k) Number K071308

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